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10/580,251	04/05/2007	Fabrizio Dolfi	29048SUS0X PCT	2049

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EXAMINER	
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ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
08/04/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)
	10/580,251	DOLFI ET AL.
	Examiner	Art Unit
	GIGI HUANG	1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 20-31* is/are pending in the application.

4a) Of the above claim(s) *1-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,17 and 20-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

Status of Application

1. The response filed October 29, 2010 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claims 16-17, 20-21 have been amended.

   b. Claims 18-19 have been cancelled.

2. Claims 1-17, 20-31 are pending in the case.

3. Claims 16-17, 20-31 are present for examination.

4. All grounds not addressed in the action are withdrawn or moot as a result of amendment.

Grounds of Rejection and Objection

Claim Objections

5. Claim 17 is objected to because of the following informalities: the claim identifier is incorrect. It should be "Currently amended" instead of "previously presented".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 25 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims recite the term "cosmetic active agent" wherein there is no description as to what materials would constitute a "cosmetic active agent". There are also no structural identifying characteristics for the compounds. Therefore, the claimed invention is not supported by adequate written description.

Response to Arguments

Applicant's arguments filed 10/29/2010 have been fully considered but they are not persuasive. Applicant asserts that the term is known in the art and cites Kirk-Othmer as a reference that there are known skin care products recognized as cosmetic actives. This not persuasive as Kirk-Othmer recite conditioners (e.g. humectants), moisturizers, and sunscreens, that Applicant is arguing to be cosmetic actives but are currently recited in the claims, and are addressed to be distinct from the grouping of cosmetic actives which goes to the issue of written description and indefiniteness as addressed previously. It is also noted that Kirk-Othmer addresses skin care products such as baby preparations (e.g. 9.1 table) which are product preparation forms, not cosmetic active agents which are recited by the claims as the cosmetic active is an additive to the preparation, not the preparation form. There are also no structural identifying characteristics for the actives/compounds recited.

Accordingly, the rejection stands.

7. Claims 25 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims recite the term "skin calmative and protective agents" wherein there is no description as to what materials would constitute a "skin calmative and protective agents ", it excludes sunscreens which are recited separately. There are also no structural identifying characteristics for the compounds. Therefore, the claimed invention is not supported by adequate written description.

Response to Arguments

Applicant's arguments filed 10/29/2010 have been fully considered but they are not persuasive. Applicant asserts that the term is known in the art and cites the specification Page 6 addressing skin calmative and protective agents such as allantoin as support for written description. This not persuasive as the claims are directed to a compound defined by desirable characteristics or properties, whereas the application provides support for only one compound within the scope of what is claimed. Additionally, allantoin is a known humectant wherein humectants are recited in the claim as a distinct group from skin calmative and protective agents which goes to the issue of written description and leads to indefiniteness as addressed previously (e.g. one cannot ascertain the metes and bounds when allantoin is a known humectant and Applicant has is as a skin calmative and protective agent, which is listed as distinct from

humectants). There is no evidence that there is any per se structure/function relationship and a single disclosed compound is not a representative number of compounds to support written description for the generic recitation in the absence of sufficient recitation of distinguishing identifying characteristics. Therefore, the claimed invention is not supported by adequate written description.

Accordingly, the rejection stands.

8. Claims 25 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims recite the term "pro-penetrating agents" wherein there is no description as to what materials would constitute a "pro-penetrating agents ". There is also no description as to what is a pro-penetrating agent. There are also no structural identifying characteristics for the compounds. Therefore, the claimed invention is not supported by adequate written description.

Response to Arguments

Applicant's arguments filed 10/29/2010 have been fully considered but they are not persuasive. Applicant cites a section of U.S. 7316810 which defines a specific formula for pro-penetrating agents and asserts that it fulfills Applicant's written description requirement. This not persuasive as fulfilled written description in an unrelated and different application/patent with the definition for a specific formula for

propenetrating agents does not preclude Applicant's burden to fulfill their own written description for what is encompassed by the term. The referenced Patent is not even related to the instant application continuity data and does not provide written description for the claimed term.

Accordingly, the rejection is maintained.

9. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claim recites the inclusion of an "immunosuppressant product". The claim covers all compounds having these characteristics or properties, but there is no evidence that there is any per se structure/function relationship or structural identifying characteristics disclosed for the group. In fact, the claims are directed to what the compound does, but not what it is wherein addresses compounds not yet discovered that are not in Applicant's possession. As addressed by the screening process of Shaw et al. (U.S. Pat. Pub. 2009/0221568, Abstract) and compounds of Beckmann et al. (U.S. Pat. Pub. 2010/0081682) which is found after Applicant's date of filing, wherein Applicant is not in possession for the scope claimed at the time of filing. Therefore, the claimed invention is not supported by adequate written description.

Response to Arguments

Applicant's arguments filed 10/29/2010 have been fully considered but they are not persuasive. Applicant asserts that immunosuppressant agents are known and the listing previously submitted complies with the written description requirement. This is not persuasive as the claim is not to a immunosuppressant agent but to an immunosuppressant product, even if not the case, Applicant is not in possession of the full scope of the claimed term as it encompasses compounds that were discovered or yet to be found after the date of filing as see by Shaw and Beckmann wherein Applicant was not in possession of the those compounds at the time of filing.

Accordingly, the rejection stands.

10. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claim recites the inclusion of an "antiproliferative agent". The claim covers all compounds having these characteristics or properties, but there is no evidence that there is any per se structure/function relationship or structural identifying characteristics disclosed for the group. In fact, the claims are directed to what the compound does, but not what it is. It encompasses compounds not yet discovered and are not in Applicant's possession. This is demonstrated by the screening process of Shaw et al. (U.S. Pat. Pub. 2009/0221568,

Abstract, anti-neoplastic is also anti-proliferative) and Wood et al. (U.S. Pat. Pub. 2009/0215805, paragraph 85) which is submitted after Applicant's date of filing; wherein Applicant was not in possession of the scope claimed at the time of filing. Therefore, the claimed invention is not supported by adequate written description.

Response to Arguments

Applicant's arguments filed 10/29/2010 have been fully considered but they are not persuasive. Applicant argues that anti-proliferative drugs are for chemotherapy and recites alkylating, antibiotic, and hormones for chemotherapy as antiproliferative agents. This not persuasive as the specification does not describe antiproliferative agents to be for chemotherapy and there is no description for what compounds would be encompassed by the term. It is noted that it is well known in the art that many conditions are related to proliferation and a general search cited pulmonary hypertension, retinopathy, and neovascular glaucoma which is not consistent with Applicant's arguments and is confusing which goes to the issues of written description and indefiniteness.

Accordingly, the rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 17, 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. The claims recite the term "treating at least one of a third stage and fourth stage of rosacea" but is dependent from claim 16 which is directed to at least one of a first stage and second stage of rosacea wherein the claims lack antecedent basis. It does not allow one of skill in the art to ascertain the metes and bounds.

12. Claims 17, 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 recite the term "treating at least one of a third stage and fourth stage of rosacea is the third stage of rosacea" which is confusing as written as it directs to at least one and then recites a stage. It does not allow one of skill in the art to ascertain the metes and bounds. For purposes of expediting examination, claim 20 is treated at directed to the third stage of rosacea.

Claim 21 recite the term "treating at least one of a third stage and fourth stage of rosacea is the fourth stage of rosacea" which is confusing as written as it directs to at least one and then recites a stage. It does not allow one of skill in the art to ascertain the metes and bounds. For purposes of expediting examination, claim 21 is treated at directed to the fourth stage of rosacea.

13. Claims 25 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. The claims recite the term "cosmetic active agent" wherein it is unclear what materials would constitute a "cosmetic active agent", it does not allow one of skill in the art to ascertain the metes and bounds.

Response to Arguments

There are no arguments presented but the issues regarding the written description and the resulting indefiniteness are addressed above.

Accordingly, the rejection stands.

14. Claims 25 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the term "skin calmative and protective agents" wherein it is unclear what materials would constitute a "skin calmative and protective agents". The term is confusing and it excludes sunscreens which are recited separately. It does not allow one of skill in the art to ascertain the metes and bounds.

Response to Arguments

There are no arguments presented but the issues regarding the written description and the resulting indefiniteness are addressed above.

Accordingly, the rejection stands.

15. Claims 25 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. The claims recite the term "pro-penetrating agents" wherein it is unclear what materials would constitute "pro-penetrating agents", it does not allow one of skill in the art to ascertain the metes and bounds.

Response to Arguments

There are no arguments presented but the issues regarding the written description and the resulting indefiniteness are addressed above.

Accordingly, the rejection stands.

16. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the phrase "obtained by dispersing a fatty phase in an aqueous phase (O/W) or, conversely, (W/O)" wherein it is unclear what it is referring to as a pharmaceutical form. It appears to be a reference to the emulsion as a product by process but it is unclear what it is actually addressing. It does not allow one of skill in the art to ascertain the metes and bounds.

Response to Arguments

There are no arguments presented but the issues regarding the written description and the resulting indefiniteness are addressed above.

Accordingly, the rejection stands.

The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

> Subject to the [fifth paragraph of 35 U.S.C. 112], a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

17. Claims 17, 20-21 are rejected under 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends. The claims recite the term "treating at least one of a third stage and fourth stage of rosacea" but is dependent from claim 16 which is directed to at least one of a first stage and second stage of rosacea claim 16 is closed to the stages of the disease, the dependent claims broaden the scope of the claim Applicant may cancel the claim(s), amend the claim(s) to place the claim(s) in proper dependent form, rewrite the claim(s) in independent form, or present a sufficient showing that the dependent claim(s) complies with the statutory requirements.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claim 16-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arkin et al. (WO 02/074290) in view of Bannwarth et al. (Tissue and systemic diffusion of idrocilamide after cutaneous administration).

The translation of Bannwarth is included and all references are to the translation.

Arkin et al. teaches a method of treating rosacea, a chronic inflammatory disorder, by topically administering a composition comprising a nonsteroidal anti-inflammatory drug. The composition can be a single nonsteroidal anti-inflammatory or a combination of them. The composition can be in conjunction with other conventional rosacea-treating agents preferably with metronidazole. See Examples 2, 4, 5 for the amounts of the nonsteroidal and the additives of the instant claims. Arkin teaches that rosacea has various dermatological manifestations (Page 4) encompassing the various stages. Presentations including flushing, erythema, telangiectasia, pustules, etc.

Patients in the different stages of rosacea aged 21-70 were treated with improvement (see Page 4, 9-15). The patient population encompass the various claimed stages as defined by the instant specification (see Page 2) which addresses that stage 1 is about 20years old, stage 2 is about 30 years old, stage 3 is about 40 years old, and stage 4 is about 50 years old or later fulfilling the instant claims. Additionally as Arkin teaches that the composition is useful for prevention and treatment of the different manifestations of rosacea (Page 1 and 4), it would be *prima facie* obvious to one of skill in the art to use it for the different manifestations/stages of rosacea with a reasonable expectation of success.

Arkin does not expressly teach the inclusion of idrocilamide.

Bannwarth et al. teaches the anti-inflammatory properties of idrocilamide are known and that its topical application was effective. There was a reduction in the pain intensity and concentration of idrocilamide in the area. Bannwarth also teaches that the

concentrations are similar when done with a diclofenac gel which is also a functionally equivalent nonsteroidal. Bannwarth also teaches that the physicochemical characteristics of idrocilamide as favors its passage through the epidermis (Abstract, Page 2-3, Results Page 4-6, Discussion Page 6-8). It is noted that Applicant cites idrocilamide is known to be an arylpropionic acid NSAID in the instant specification (see Page 3 of instant specification).

It would have been obvious to one of skill in the art at the time of the invention to include idrocilamide in the invention of Arkin, as motivated by Bannwarth, as Bannwarth teaches that idrocilamide is an effective topical NSAID and the general teaching of Arkin is for the topical use of NSAIDS for rosacea. It also would have been obvious to substitute the idrocilamide for the diclofenac in the examples of Arkin as Bannwarth teaches the NSAIDS to be functionally equivalent. It is desirable for manufacturers to have functionally equivalent choices to substitute a functionally equivalent NSAID for another when motivated by pricing and availability and topical penetration of the NSAID used to produce the final product, and the physicochemical characteristics of idrocilamide as shown by Bannwarth favors its passage through the epidermis. The skilled artisan would have had a reasonable expectation of successfully treating rosacea by topically applying the composition comprising the NSAID.

Response to Arguments

Applicant's arguments filed 10/29/2010 have been fully considered but they are not persuasive. Applicant's arguments centered on the assertion that the trial of Arkin is to the third stage of rosacea. This is not persuasive as Applicant has defined stage 1 is

at about 20 years old, stage 2 is about 30 years old, stage 3 is about 40 years old, and stage 4 is about 50 years old or later; and the clinical trial teaches the patient pool to be from 21-70 meeting the claims as defined by the specification. Additionally the trial had patients with various dermatological manifestations of rosacea (Page 4) which implicitly are different stages of the conditions. The patients were also measured for erythema and telangiectasia which are hallmarks of stage 2 as defined by Applicant.

Accordingly, the rejection stands.

Conclusion

19. Claims 16-17, 20-31 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:00AM-6:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENIVASAN PADMANABHAN can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GiGi Huang/
Examiner, Art Unit 1627
/Zohreh A Fay/
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